

## FOR IMMEDIATE RELEASE

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# ArthroTAK Receives FDA 510(k) Clearance for the ArthroTAK™ Tendon Anchor Kit, a Sutureless, Soft-Tissue Fixation System for Biceps Tenodesis

*Drive. Deploy. Done. — A New Standard of Simplicity, Speed, and Reliability for Sports Medicine Surgeons*

**ORLANDO, FL — 5/4/2026** - ArthroTAK, LLC, an Orlando-based medical device company, today announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the ArthroTAK™ Tendon Anchor Kit. The clearance authorizes the company to market the device in the United States for soft-tissue to bone fixation in open and arthroscopic biceps tenodesis procedures.

The ArthroTAK Tendon Anchor Kit is a sterile, single-use, sutureless soft-tissue-to-bone fixation system. Its PEEK implant is delivered through the tendon and into bone in a single, mallet-driven step, then locked into place by simple clockwise rotation of the inserter knob. The system eliminates the need for sutures, suture passers, knot-tying, or power equipment, significantly reducing surgical complexity and procedural time.



“Receiving FDA 510(k) clearance is a defining milestone for ArthroTAK and the culmination of years of work by our engineering team, surgeon advisors, and partners,” said Justin J. Kaler, General Manager of ArthroTAK. “Biceps tenodesis is a high-volume sports medicine procedure that has long been dominated by complex, suture-dependent techniques. ArthroTAK gives surgeons a faster, simpler, and more reproducible option, and gives Ambulatory Surgical Centers (ASCs) and hospitals a way to drive efficiency without compromising fixation strength.”

Biceps tenodesis is performed more than 220,000 times each year in the United States, with many cases now migrating from hospital outpatient settings to ASCs, where procedural efficiency and per-case cost have become critical drivers of adoption.

Benchtop testing has demonstrated ultimate fixation strength competitive with leading marketed biceps tenodesis devices, well above the upper bound of normal physiological loads. The



implant is compatible with all three standard surgical approaches: arthroscopic suprapectoral, arthroscopic high-groove, and open subpectoral. ArthroTAK can also be deployed percutaneously or through an 8 mm or larger cannula.

FDA 510(k) clearance allows ArthroTAK to begin commercial distribution of the Tendon Anchor Kit through their independent distributor partners. ArthroTAK's product roadmap extends well beyond biceps tenodesis. The same modular fixation platform is being actively evaluated for additional sports medicine applications, to address an annual procedural volume of more than three million cases globally.

## **About ArthroTAK**

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ArthroTAK, LLC is an Orlando-based medical device company developing innovative, sutureless soft-tissue fixation technology for sports medicine and orthopedic surgery. The company's flagship product, the ArthroTAK™ Tendon Anchor Kit, is a single-use, single-step PEEK implant system designed to simplify bone-to-tendon fixation, reduce surgical time, and lower procedural costs. To learn more, visit [www.arthrotak.com](http://www.arthrotak.com).

## **Forward-Looking Statements**

*This press release contains forward-looking statements regarding ArthroTAK's product plans, commercial strategy, and future market expansion. Actual results may differ materially from those projected. ArthroTAK does not undertake any obligation to update these statements except as required by law.*

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